K955605

immuno concepts

APR 19 1996

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* 510(k) SUMMARY *
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Date Prepared: December 4, 1995
Contact Person: Eric S. Hoy, Ph.D.
Name of Device:

- **Trade Name** - RELISA® Jo-1 Antibody Test System
- **Common Name** - Jo-1 Antibody Test System
- **Classification Name** - Extractable Antinuclear Antibody (21 CFR 866.5100)

Legally marketed device with which this device has been shown to be equivalent:
RELISA® ENA Antibody Screening Tests System, K935129

Description:
This is an enzyme immunoassay for the detection of antibodies to nuclear antigen Jo-1 in human serum.

Intended Use:
This test system is for in vitro diagnostic use for the detection of antibodies to nuclear antigen Jo-1 in human serum.

Summary of Technological Characteristics Compared to the Predicate Device:
This device is identical to the predicate device with the following exceptions:
a) The predicate device has six different autoantigens coated on individual microwells; the present device has only Jo-1 autoantigen coated on the microwells.
b) The predicate device includes a procedure control well on each strip of microwells, the present device includes a calibrator serum in the kit.

Description of Laboratory Data That Indicate Substantial Equivalence:
For direct determination of relative sensitivity and specificty, we used the Immuno Concepts RELISA® Screening Assay (K935129) as a reference method. The data obtained in this comparison are shown in the following Table.

Immuno Concepts Incorporated · 9779 "D" Business Park Drive · Sacramento, CA 95827
(916) 363-2649 · (800) 251-5115 · FAX: (916) 363-2843

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Table 1. Detection of antibodies to the Jo-1 autoantigen.

		Immuno Concepts RELISA® Screening Assay		
		Positive	Borderline	Negative
Immuno Concepts RELISA® Jo-1	Positive	21	1	0
	Borderline	2	4	1
	Negative	0	0	140

If we assume that "borderline" results are actually positive, these data yield the following statistics: relative sensitivity, 100.0%; relative specificity, 99.3%; and overall agreement, 99.4%

In accordance with 21 CFR 807.92(b)(3), we conclude from these data that the present device is substantially equivalent to the predicate device.